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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/879,188	06/12/2001	Robert Shartle	LFS-115	4059

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EXAMINER

ALEXANDER, LYLE

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 07/07/2003

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/879,188

Applicant(s)

SHARTLE ET AL.

Examiner

Lyle A Alexander

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-53 is/are pending in the application.
- 4a) Of the above claim(s) 21-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-20 and 33-53 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-53 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 46.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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The claims as originally filed did not include claim 49. The claims have been renumbered 1-53 respectively under Rule 126.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-20 and 33-53, drawn to a sampling device having a skin-piercing member, an electrochemical cell and a hydrophilic transfer medium, as well as the associated method of use classified in class 128.
- II. Claims 21-32, drawn to a array of micro-needles having 2 layers of conductive material, classified in class 600.

The inventions are distinct, each from the other because of the following reasons:

Inventions II and I are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the electrochemical cell is not required. The subcombination has separate utility such as an electrochemical cell.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

During a telephone conversation with Ms. LaSalle on 6/26/03 a provisional election was made with traverse to prosecute the invention of group I, claims 1-20 and

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33-54. Affirmation of this election must be made by applicant in replying to this Office action. Claims 21-32 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-20, 33-39 and 49-53 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-33 of U.S. Patent No. 6,501,976. Although the conflicting claims are not identical, they are not patentably distinct from each other because both are directed to a device for

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determination of blood glucose comprising means to draw blood, a porous electrode, a gel matrix and means to correlated the measured value to a blood glucose level.

Claims 1-20 and 33-53 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of copending Application No. 09/879,146. Although the conflicting claims are not identical, they are not patentably distinct from each other because both are directed to a device and method for the determination of blood glucose comprising means to draw blood, a porous electrode, a gel matrix and means to correlated the measured value to a blood glucose level.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-8,20 and 33-53 provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-57 of copending Application No. 09/878,742. Although the conflicting claims are not identical, they are not patentably distinct from each other because both are directed to a device and method of use for the determination of blood glucose comprising means to draw blood, a porous electrode, a gel matrix and means to correlated the measured value to a blood glucose level..

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 9-19 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-39 of copending Application No. 09/878,742 in view of Joseph.

Copending Application No. 09/878,742 teaches to a device for determination of blood glucose comprising means to draw blood, a porous electrode, a gel matrix and means to correlated the measured value to a blood glucose level. Copending Application No. 09/878,742 is silent to the claimed porous electrode.

Joseph teaches in column 3 that it is known to use porous electrodes in devices that determine glucose in body fluids. Porous electrodes have the advantage of permitting passage of interstitial fluid, which facilitates real time analysis.

It would have been within the skill of the art to modify copending Application No. 09/878,742 in view of Joseph and use a porous electrode to gain the above advantages.

This is a provisional obviousness-type double patenting rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2,5-8,20 and 33-53 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Gough.

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Gough teach an electrochemical cell for the determination of glucose in blood comprising a housing(10), a fine hollow needle suitable for piercing the skin, oxygen sensors(18 and 16) and an oxidase enzyme embedded in a porous gel(20) that surrounds the sensors. Column 3 lines 1-5 teach the gel matrix can be an acrylamide or acrylic polymer. A reference electrode(28) is also taught. Column 4 lines 3-20 teach the amount of glucose is proportional to the output of the two sensors. Figure 1 teaches that adjustments in current have a differential effect on the measuring device.

The claimed skin-piercing member has been read on the taught fine hollow needle suitable for piercing the skin. The claimed electrochemical cell has been read on the sensors(16 and 18). The claimed constituent transfer medium has been read on the taught acrylamide or acrylic polymers. The claimed means for sending an electrical signal and software algorithm have been read on the taught sensor output. The claimed control means have been read on the taught reference electrode(28). The claimed hand held configuration has been read on the teaching the device(10) is held up to the skin.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 3-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gough in view of Nitzan.

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See Gough supra.

Gough is silent to the claimed natural gel matrix of agarose or starch.

Nitzan teach an electrochemical glucose sensor. Column 6 lines 49-53 teach "many types of polymers are suitable ones such as for examples polyacrylamide , polyacrylic acid agarose starch...". The Office has read this passage as teach the equivalence of polyacrylamide , polyacrylic acid, agarose and starch.

It would have been within the skill of the art to modify Gough in view of Nitzan and use other equivalent gel materials such as agarose or starch as experimental design choice.

Claims 9-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gough in view of Joseph.

See Gough supra.

Gough is silent to the claimed porous electrode.

Joseph teaches in column 3 that it is known to use porous electrodes in devices that determine glucose in body fluids. Porous electrodes have the advantage of permitting passage of interstitial fluid, which facilitates real time analysis.

It would have been within the skill of the art to modify Gough in view of Joseph and use a porous electrode to gain the above advantages.

Gough is silent to the claimed porosity/pore size and distance between the electrodes.

The court decided In re Boesch (205 USPQ 215) that optimization of a result effective variable is ordinarily within the skill of the art. A result effective variable is one

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that has predictable and well-known results. The choice of porosity of the electrodes as well as the spacing of the electrodes would have been result effective variables. It would have been within the skill of the art to modify Gough in view of Joseph and select the porosity of the electrodes as being 100-150 microns and the electrode spacing of 100-500 angstroms as optimization of result effective variables.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lyle A Alexander whose telephone number is 703-308-3893. The examiner can normally be reached on Monday, Wednesday and Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 703-308-4037. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9319 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0651.



Lyle A Alexander
Primary Examiner
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June 30, 2003